



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED *RTK*

May 15, 1998

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 27

Dean Issacson
General Manager
Western Consolidated Cooperative
121 Central Avenue
Sunburg, Minnesota 56289

Dear Mr. Issacson:

A recent inspection of your medicated feed mill located at Sunburg, Minnesota, by Richard Estum on behalf of the Food and Drug Administration (FDA) found significant deviations from Current Good Manufacturing Practice (CGMP) regulations for Medicated Feeds [Title 21, Code of Federal Regulations, Part 225 (21 CFR 225)]. Such deviations cause medicated feeds being manufactured at your facility to be adulterated within the meaning of Section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found the following deviations:

1. A daily inventory record for each drug used shall be maintained and shall list by manufacturer's lot number or the feed manufacturer's shipment identification number at least the following information: the quantity of drug on hand at the beginning and end of the work day (the beginning amount being the same as the previous day's closing inventory if this amount has been established to be correct); the quantity shall be

Page Two

Dean Issacson

May 15, 1998

determined by weighing, counting, or measuring, as appropriate [21 CFR 225.42(b)(6)]. [REDACTED] has the wrong lot number and [REDACTED] and [REDACTED] had inaccurate inventories. A daily comparison between the actual amount of the drug used and the theoretical drug usage is not done.

2. For feeds requiring an approved Mill License for their manufacture and marketing, at least three representative samples of medicated feed containing each drug or drug combination used in the establishment shall be collected and assayed by approved official methods, at periodic intervals during the calendar year, unless otherwise specified in this chapter [21 CFR 225.58(b)(1)]. Assays are not being done.
3. All equipment shall be maintained in a reasonably clean and orderly manner [21 CFR 225.30(b)(2)]. There was a lot of build-up on the walls and paddles of the horizontal mixer.

The above is not intended to be an all-inclusive list of CGMP violations. As a manufacturer of medicated and non-medicated feeds, you are responsible for ensuring that your overall operation and the products you manufacture and distribute are in compliance with the law. Enclosed is a copy of the CGMP regulations that apply to your facility [21 CFR 225.1-120].

You should take prompt action to correct these CGMP violations and you should establish procedures whereby such violations do not recur. Failure to promptly correct these CGMP violations may result in regulatory and/or administrative sanctions. These sanctions include, but are not limited to, seizure, injunction and/or notice of opportunity for a hearing on a proposal to withdraw approval of your mill license under Section 512(m)(4)(B)(ii) of the Act and 21 CFR 514.115(c)(2).

This letter constitutes official notification under the law. Based on the result of the inspection, evaluated together with the evidence before FDA when the Mill License was approved, the methods used in, or the facilities and controls used for, the manufacture, processing, and packing of medicated feed are inadequate to assure and preserve the identity, strength, quality, and purity of the new animal drugs therein.

Page Three

Dean Issacson
May 15, 1998

This letter notifies you of our findings and provides you an opportunity to correct the above deficiencies.

You should notify this office in writing within 15 working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the CGMP violations and prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Compliance Officer Robert P. Snell at the address on the letterhead.

Sincerely,

A handwritten signature in black ink, appearing to read "James R. Rahto", is written over the typed name.

James R. Rahto
Director
Minneapolis District

RPS/ccl

Enclosure: 21 CFR 225.1-125